Aadi Bioscience to Present at Ladenburg Thalmann 2021 Virtual Healthcare Conference

July 7, 2021

LOS ANGELES, July 07, 2021 (GLOBE NEWSWIRE) — Aadi Bioscience, Inc. (“Aadi”), a privately-held clinical-stage biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced that Founder, Chief Executive Officer and President, Neil Desai, Ph.D., will present at the Ladenburg Thalmann 2021 Virtual Healthcare Conference on Tuesday, July 13, 2021.

Presentation Information:

Date: Tuesday, July 13, 2021

Time: 2:30 – 2:55 pm ET

Location: Track 2

The live webcast can be accessed here: https://wsw.com/webcast/ladenburg7/aadi/2358021.

About Aadi Bioscience and FYARRO™

Aadi is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi’s primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in *TSC1* or *TSC2* genes, where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. Aadi’s product FYARRO ™ (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009) is an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, mTOR target suppression, and enhanced tumor growth suppression over other mTOR inhibitors in preclinical models.[1]

Aadi’s registration trial of FYARRO in advanced malignant PEComa (the AMPECT trial) demonstrated meaningful clinical efficacy in malignant PEComa, a type of cancer with the highest known alteration rate of *TSC1* or *TSC2* genes. In long-term follow-up data presented on the AMPECT study at ASCO 2020[2], an analysis of 31 RECIST-evaluable advanced PEComa patients treated with FYARRO demonstrated a 39% (95% CI: 22%-58%) independently reviewed confirmed overall response rate (ORR) including 1 complete response (CR) and 11 partial responses (PRs). The median duration of response had not yet been reached (range 5.6 to 42.4+ months, with 50% of the responders having a response duration that is 25.8 months or longer) and the majority of the responders were still on treatment. The response rate in the patients with metastatic disease was 46% (12/26, 95% CI: 27%-67%). In the patients with locally advanced, inoperable disease, 2 of 5 (40%) were able to undergo surgery following tumor shrinkage and remained disease-free in excess of 3 years. The median progression-free survival was 8.9 months (95% CI: 5.5 – not reached) and the one-year overall survival rate was 89%. In an exploratory analysis of the subset of patients with *TSC1* or *TSC2* alterations, the independently reviewed response rate was 64% (9/14, 95% CI: 34%-87%). Thirty-four patients were evaluable for safety. Most treatment-related adverse events (TRAEs) were grade 1 or 2. No grade 4 or 5 TRAEs occurred. The most common nonhematologic TRAEs of any grade were mucositis (79%), fatigue (59%), and rash (56%). The most common hematologic TRAEs were anemia (47%) and thrombocytopenia (32%). Noninfectious pneumonitis occurred in 18% of patients and was grade 1 or 2. Two patients stopped therapy due to a TRAE (grade 2 anemia and grade 1 cystitis). Dose reductions occurred in 13/34 (38%) of patients; 11 patients had a dose reduction from 100 mg/m^2 to 75 mg/m^2 and 2 patients had a dose reduction to 56 mg/m^2. FYARRO has received Breakthrough Therapy, Fast-Track and Orphan Designations from the U.S. Food and Drug Administration (FDA). A rolling New Drug Application (NDA) submission was completed in May 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations, and following discussions with the FDA, Aadi plans to submit an Investigational New Drug application (IND) for a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations and initiate the study by the end of 2021. Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States. More information is available on the Aadi website at www.aadibio.com.

References:

[1] AACR 2019 Abstract: https://cancerres.aacrjournals.org/content/79/13_Supplement/348

[2] ASCO 2020 Abstract: https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.11516?af=R

Contacts:

Investors

Irina Koffler
ikoffler@lifesciadvisors.com

- A replay will also be available at this link and posted on Aadi's website within the Investors & News/ Events & Presentations section.